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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/720,025

11/21/2003

Elliot Lorne Chaikof

133-02

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05/08/2009

GREENLEE WINNER AND SULLIVAN P C

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BOULDER, CO 80301

EXAMINER

NOAKES, SUZANNE MARIE

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

05/08/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/720,025	<b>Applicant(s)</b> CHAIKOF ET AL.	
	<b>Examiner</b> SUZANNE M. NOAKES	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-76 is/are pending in the application.
- 4a) Of the above claim(s) 12-32,35,36 and 41-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-11,33,34 and 37-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/05/2009</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

1. The amendments to the claims and response to the previous Office action (a Non-Final Office action) are acknowledged. Applicants have cancelled claim 2 and amended claim 1. Thus, claims 1 and 3-76 are pending; claims 12-32, 36, 36 and 41-76 remain withdrawn from consideration for the reasons recited in the previous Office action. Claims 1, 2-11, 33, 34 and 37-40 are subject to Examination on the merits.

### ***Priority***

2. Acknowledgment is made of applicant's claim for foreign priority based on an applications filed in Canada, Japan and Australia on 01/29/2003, 04/01/2003 and 08/27/2003, respectively. The certified priority documents have been received.

### ***Information Disclosure Statement***

3. The information disclosure statements (IDS) submitted on 05 February 2009.

### ***Withdrawal of Previous Rejections/Objections***

4. Any objection/rejection previously recited and not reiterated below is hereby withdrawn.

5. The objection to the specification for not complying with the sequence rules is withdrawn in view of Applicants amendments to p. 7, paragraph 00020.

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6. The rejection of claims 1 and 11 under 35 U.S.C. 102(b) as being anticipated by Capello et al. (J. of Controlled Release, 1998, 53:105-117) is withdrawn in view of the amendments to the claims which require a three block co-polymer (two hydrophobic end blocks and one middle hydrophilic).

7. The rejection of claims 1 and 11 under 35 U.S.C. 102(b) as being anticipated by Lee et al. (Adv. Materials, 2000, 12(15):1105-10 – cited on IDS from 1/21/04) is withdrawn in view of the amendments to the claims which require a three block co-polymer (two hydrophobic end blocks and one middle hydrophilic).

### ***Maintained Rejections***

#### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 1, 3, 4, 8, 11, 33, 34 and 37-40 are rejected under 35 U.S.C. 102(a) as being anticipated by Wright and Conticello (Adv. Drug Deliv. Rev., Oct. 2002, 54:1057-73 – cited on IDS from 1/21/04).

Wright and Conticello teach synthetic protein copolymers of the construction AB and BAB, wherein A is a hydrophilic block and B is a hydrophobic block. Various representative B and A blocks are taught in Table 2, p. 1060. It is noted that the B blocks are of the form: [VPAVG(IPAVG)<sub>4</sub>]<sub>16</sub>. Since claim 1 open comprising language, it

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is deemed that this sequence is encompassed in the instant SEQ ID NO: 12 (and is SEQ ID NO: 11). The copolymers form microparticles (e.g. self-assembled gels – see Figure 7) and also have inverse transition temperatures at about 25°C (see p. 1068, 1<sup>st</sup> column, 1<sup>st</sup> paragraph).

10. Claims 1, 3, 5, 33, 34 and 37-40 are rejected under 35 U.S.C. 102(a) as being anticipated by Wright et al. (Adv. Funct. Materials, Feb. 2002, 12:149-54 – cited on IDS of 1/21/04).

Wright et al. teach synthetic protein copolymers of the construction AB and BAB, wherein A is a hydrophilic block and B is a hydrophobic block. Scheme 1 on p. 149 comprises two different copolymers of the BAB form wherein copolymer 1 *comprises* SEQ ID NO: 18 of claim 5 as the middle hydrophilic block. Both copolymers display transition temperatures at about 21 and 23°C, respectively (see p. 150, 1<sup>st</sup> column, last paragraph and Figure 3). Both copolymers form microparticles having micellar particles (e.g. spherical shape)-(see p. 152, last paragraph).

***New Rejections – Not Necessitated by Amendments***

***Claim Rejections - 35 USC § 112 – 1<sup>st</sup> paragraph***

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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12. Claims 1, 3-5, 8-11, 33, 34 and 37-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are generically drawn to a synthetic protein copolymer comprising at least one hydrophilic block and two end blocks which are hydrophobic, of the structure BAB, wherein B=hydrophobic end block and A=hydrophilic middle block. Said "blocks", either the hydrophilic or hydrophobic, can have any structure/amino acid sequence and furthermore is not required to have any sort of function. Even for those claims which do limit either the A or B blocks (e.g. claims 4 or 9, for example), the combination of structures for the other blocks is endless and enormous and extremely variable in structure. Thus, the claims are drawn to an enormous and variable genus of protein copolymers with very little structural requirements and which are not required to have any sort of function. The specification, however, describes only a limited number of species for the protein co-polymers wherein said hydrophilic blocks are selected from SEQ ID NOs: 14, 15, 18, 21, 23, 24, 25, 30, 33, 35, 38, 41, 42, 43 and 63 and the hydrophobic end blocks are selected from SEQ ID NO: 11 or 12 (although the claims only limit these hydrophobic blocks to the first end block and there is no structural requirement for the second end blocks whatsoever). However, these species, even those such as that listed in claim 6, is not considered to be representative of the

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extremely broad and variable genus of structures which further have no structural requirements whatsoever.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, at the time the invention was made, of the specific subject matter claimed. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that 'the inventor invented the claimed invention.' *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ('[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'). Thus, an applicant complies with the written description requirement 'by describing the invention, with all its claimed limitations, not that which makes it obvious,' and by using 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.' *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

MPEP § 2163 further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the

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sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." Furthermore, the courts have also held that possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features. See *University of Rochester*, 358 F.3d at 927, 69 USPQ2d at 1895.

As such the claims are deem

### ***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1, 3, 11, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by West et al. (Macromolecules, 1999, 32:241-44).

West et al. teach synthetic BAB block co-polymers wherein the A-block is a water-soluble biocompatible polymer of PEG and the B-blocks are short oligopeptides. Said co-polymers further comprise reactive acrylate groups which allows for polymerization to form cross-linked hydrogels (see p. 241, 1<sup>st</sup> col., 1<sup>st</sup> paragraph). For instance, the co-polymer in one instance NH<sub>2</sub> – (APGL) – PEG – (APGL) – NH<sub>2</sub> (see p. 242, 1<sup>st</sup> col., 1<sup>st</sup> paragraph), or wherein NH<sub>2</sub> is substituted with ACR; or Acr-(VRN) – PEG – (VRN) – Acr (see p. 242, 1st column through to 2nd column); APGL is: Ala-Pro-Gly-Leu.



***Response to Declarations***

15. The declaration filed under 37 CFR 1.132 on 04 February 2009 is insufficient to overcome the rejection of claims 1, 3, 4, 8, 11, 33, 34 and 37-40, rejected under 35 U.S.C. 102(a) as being anticipated by Wright and Conticello (Adv. Drug Deliv. Rev., Oct. 2002, 54:1057-73 – cited on IDS from 1/21/04) as set forth in the last Office action because of the following discrepancies. Although Applicants state that the non-named inventors have contributed to the pending claims in what specific manner is unclear, e.g. what are the specific contributions that each of the Inventors/Authors have had to the specific rejected claims? Does each Inventor/Author contribute to the rejected claims? It is noted that in the declaration signed by Elizabeth Wright and Vincent Conticello, it specifically states in section 6: “

That Vincent P. Conticello and Elizabeth R. Wright along with Elliot L. Chaikof, Karthik Nagapudi, William T. Brinkman, Robert A. McMillan and Sonha C. Payne have been collaborating in the conception and development of synthetic protein copolymers as presented in the pending claims of the above-referenced U.S. Patent Application No. 10/720,025 and that the Wright and Conticello reference was prepared at least in part based on this collaboration.

It is noted that an inventor need not contribute each and every pending claim, contribution to a single claim is enough to be listed as an inventor. Thus, by not establishing what the inventors/authors have done, e.g. if Wright and Conticello contributed only to, for example, pending but withdrawn claim 25, then the reference would still be applicable towards the rejection of claim 1.

16. The declaration filed under 37 CFR 1.132 on 04 February 2009 is insufficient to overcome the rejection of claims 1-3, 5, 33, 34 and 37-40 are rejected under 35

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U.S.C. 102(a) as being anticipated by Wright et al. (Adv. Funct. Materials, Feb. 2002, 12:149-54 – cited on IDS of 1/21/04) as set forth in the last Office action because of the following discrepancies. Applicants have sufficiently established that co-authors Cooper and Apakarian only made technical contributions and did not contribute any original and inventive work to the instant Invention. Applicants also state:

That only co-authors Vincent P. Conticello, Robert A. McMillan and Elizabeth R. Wright, along with co-inventors Elliot L. Chaikof, Karthik Nagapudl, William T. Brinkman, Sonha C. Payne, made original and inventive contributions to the invention as claimed in U.S. Patent Application No. 10/720,025 and in the subject matter disclosed in the Wright et al, reference cited by the Patent and Trademark Office in the Office Action of August 14, 2008 in support of the pending rejections on the basis of anticipation.

However, herein lies the discrepancy; Applicants are stating that co-inventors Elliot L. Chaikof, Karthik Nagapudl, William T. Brinkman, Sonha C. Payne, made original and inventive contributions to the invention as claimed in U.S. Patent Application No. 10/720,025 and in the subject matter disclosed in Wright et al. However, they are not listed on said publication. Applicants furthermore have to distinguish what contributions that each inventor have made to the *pending claims* and even more importantly, to the claims under rejection. By not doing so, it is impossible to distinguish if said Wright et al. reference is not in fact still by another. For instance, Wright. MacMillan and Conticello may have contributed to claim 25, but nothing to claim 1 and thus the reference would technically still by be another and the rejection stands.

***Response to Arguments***

17. Applicant's arguments filed 04 February 2009 have been fully considered but they are not persuasive.

Applicants arguments regarding the 35 U.S.C. 102(a) rejections of record have been considered but are unpersuasive to overcome the rejections of record for the reasons set forth above in the response to Applicants Declarations filed under 37 C.F.R. 1.132.

All other rejections of record have been withdrawn due to the amendments to the claims.

***Conclusion***

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE M. NOAKES whose telephone number is (571)272-2924. The examiner can normally be reached on 7.00 AM-3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SUZANNE M. NOAKES/  
Primary Examiner, Art Unit 1656  
27 April 2009